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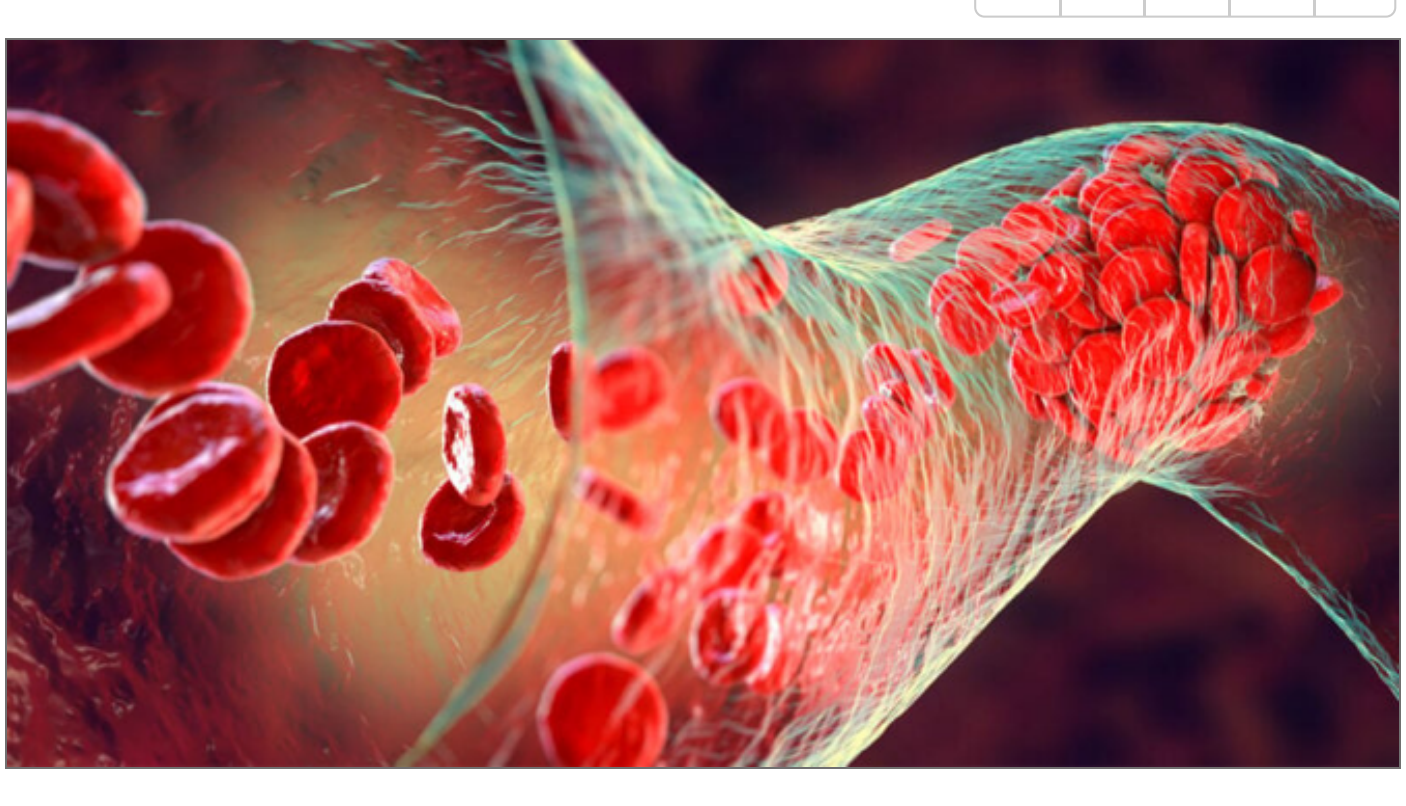
12/19/22 • COVID › NEWS

FDA Study: COVID Vaccine Linked to Blood Clotting in Elderly

Researchers at the U.S. Food and Drug Administration found that pulmonary embolism — blood clotting in the lungs — met the initial threshold for a statistical signal in elderly individuals and continued meeting the criteria after a more in-depth evaluation.

By The Epoch Times

39



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By Zachary Stieber

Pfizer's COVID-19 vaccine has been linked to blood clotting in older individuals, according to the U.S. Food and Drug Administration (FDA).

FDA researchers, crunching data from a database of elderly persons in the United States, found that pulmonary embolism — blood clotting in the lungs — met the initial threshold for a statistical signal and continued meeting the criteria after a more in-depth evaluation.

Three other outcomes of interest — a lack of oxygen to the heart, a blood platelet disorder called immune thrombocytopenia and another type of clotting called intravascular coagulation — initially raised red flags, researchers said.

More in-depth evaluations, such as comparisons with populations who received influenza vaccines, showed those three as no longer meeting the statistical threshold for a signal.

Researchers looked at data covering 17.4 million elderly Americans who received a total of 34.6 million vaccine doses between Dec. 10, 2020, and Jan. 16, 2022.

The study was published by the journal Vaccine on Dec. 1.

The FDA said it was not taking any action on the results because they do not prove the vaccines cause any of the four outcomes, and because the findings "are still under investigation and require more robust study."

Dr. Peter McCullough, chief medical adviser for the Truth for Health Foundation, told The Epoch Times via email that the new paper "corroborates the concerns of doctors that the large uptick in blood clots, progression of atherosclerotic heart disease, and blood disorders is independently associated with COVID-19 vaccination."

Pfizer did not respond to a request for comment.

How the research was done

FDA researchers, with assistance from researchers with the Centers for Medicare & Medicaid Services (CMS), analyzed data from the CMS database.

They included Medicare Fee-for-Service beneficiaries aged 65 or older who received a vaccine within the timeframe, were enrolled when they were vaccinated and were enrolled for a "clean window" of time prior to vaccination. The window was 183 days or 365 days, depending on the outcome.

About 25 million people receive the Medicare Fee-for-Service, but only about 17 million were vaccinated during the period of time studied.

Researchers used probability testing to detect an increased risk of one or more of 14 outcomes following vaccination.

The goal was to see whether vaccination may increase the risk of adverse outcomes, such as pulmonary embolism, or blood clotting in the lungs. If an outcome met a certain statistical threshold, that meant it could increase the risk.

The initial results of the safety monitoring detected an increased risk of four events, the FDA announced on July 12, 2021. They were the same four outlined in the new paper, which is the first update the agency has given on the matter since its announcement.

As of Jan. 15, 2022, 9,065 cases of a lack of oxygen to the heart — known as acute myocardial infarction — were detected, researchers revealed in the new study. As of the same date, 6,346 cases of pulmonary embolism, 1,064 cases of immune thrombocytopenia and 263 cases of coagulation were detected.

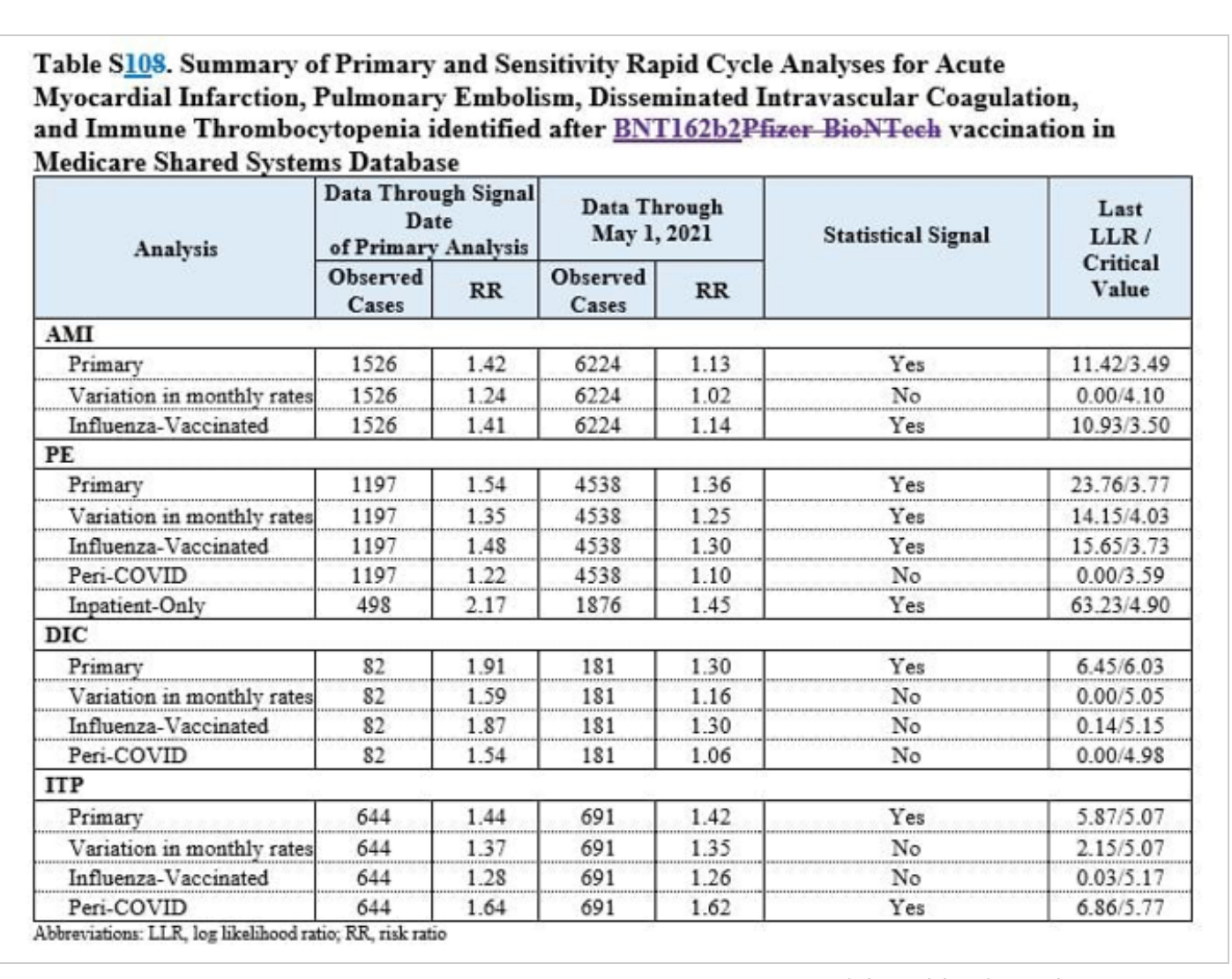

Table S108. Summary of Primary and Sensitivity Rapid Cycle Analyses for Acute Myocardial Infarction, Pulmonary Embolism, Disseminated Intravascular Coagulation, and Immune Thrombocytopenia identified after BNT162b2~~Pfizer-BioNTech~~ vaccination in Medicare Shared Systems Database

Analysis	Data Through Signal Date of Primary Analysis		Data Through May 1, 2021		Statistical Signal	Last LLR / Critical Value
	Observed Cases	RR	Observed Cases	RR		
AMI						
Primary	1526	1.42	6224	1.13	Yes	11.42/3.49
Variation in monthly rates	1526	1.24	6224	1.02	No	0.00/4.10
Influenza-Vaccinated	1526	1.41	6224	1.14	Yes	10.93/3.50
PE						
Primary	1197	1.54	4538	1.36	Yes	23.76/3.77
Variation in monthly rates	1197	1.35	4538	1.25	Yes	14.15/4.03
Influenza-Vaccinated	1197	1.48	4538	1.30	Yes	15.65/3.73
Peri-COVID	1197	1.22	4538	1.10	No	0.00/3.59
Inpatient-Only	498	2.17	1876	1.45	Yes	63.23/4.90
DIC						
Primary	82	1.91	181	1.30	Yes	6.45/6.03
Variation in monthly rates	82	1.59	181	1.16	No	0.00/5.05
Influenza-Vaccinated	82	1.87	181	1.30	No	0.14/5.15
Peri-COVID	82	1.54	181	1.06	No	0.00/4.98
ITP						
Primary	644	1.44	691	1.42	Yes	5.87/5.07
Variation in monthly rates	644	1.37	691	1.35	No	2.15/5.07
Influenza-Vaccinated	644	1.28	691	1.26	No	0.03/5.17
Peri-COVID	644	1.64	691	1.62	Yes	6.86/5.77

Abbreviations: LLR, log likelihood ratio; RR, risk ratio

One of the tables from the new paper.

The primary analysis showed a safety signal for all four outcomes. Researchers tried adjusting the numbers by using different variables.

For instance, at one point they adjusted for the variation of background rates, or the rates of each outcome in the general population prior to the pandemic. After certain adjustments — not all — the myocardial infarction, immune thrombocytopenia and intravascular coagulation ceased being statistically significant.

Pulmonary embolism, though, continued to be statistically significant, the researchers said. Pulmonary embolism is a serious condition that can lead to death.

Limitations of the study included possible false signals and possible missed signals due to factors such as parameters being specified wrongly.

The conditions that didn't trigger a signal included stroke, heart inflammation and appendicitis.

The signals were detected only after Pfizer vaccination. Analyses for signals after receipt of the Moderna and Johnson & Johnson vaccines did not show any concerns.

Moderna and Johnson & Johnson did not respond to requests for comment.

Side effects Pfizer vaccine

All three vaccines have been linked to a number of side effects. Heart inflammation is causally linked to the Moderna and Pfizer shots, experts around the world have confirmed, while Johnson & Johnson's has been associated with blood clots.

Other conditions, such as pulmonary embolism, have been reported to authorities and described in studies, though some papers have found no increase in risk following vaccination.

Approximately 4,214 reports of post-vaccination pulmonary embolism, including 1,886 reports following receipt of Pfizer's vaccine, have been reported to the U.S. Vaccine Adverse Event Reporting System, or VAERS, as of Dec. 9.

As of the same date, 1,434 reports of post-vaccination myocardial infarction, including 736 following receipt of Pfizer's vaccine; 469 reports of post-vaccination immune thrombocytopenia, including 234 following receipt of Pfizer's vaccine; and 78 reports of post-vaccination intravascular coagulation, including 42 after receipt of Pfizer's vaccine, have been reported.

Reports to the system can be made by anybody, but most are lodged by healthcare workers, studies show. The number of reports is an undercount, according to studies.

The new study states that the FDA "strongly believes the potential benefits of COVID-19 vaccination outweigh the potential risks of COVID-19 infection." No evidence was cited in support of the belief.

The FDA is set to meet with its vaccine advisory panel in January 2023 about the future of COVID-19 vaccines, as the vaccines have been performing much worse against Omicron and its subvariants.

McCullough told The Epoch Times:

> "A shortcoming of the CMS surveillance system is that it did not capture prior and subsequent SARS-CoV-2 infection which accentuate the cumulative risk of COVID-19 vaccination.
>
> "Given the large number of individuals who have been vaccinated, the population attributable fraction of medical problems ascribed to the vaccines is enormous. I have concerns over the future burden to the healthcare system as a consequence of mass indiscriminate COVID-19 vaccination."

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Zachary Stieber is a senior reporter for The Epoch Times based in Maryland. He covers U.S. and world news.

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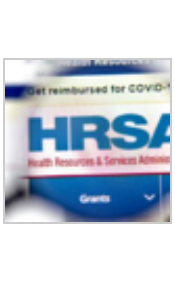

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CheeseEdWest
10 days ago
I am struck by how kind the author and Dr. McCulloch are in their tone and content. The FDA doesn't deserve it, as they do their best to bob and weave around their responsibility.
16 0 • Reply • Share ›

Darby O'Gill → CheeseEdWest
10 days ago
That's what guilty people do, bob and weave. They bob around the truth and weave deceit.
5 0 • Reply • Share ›

farmerflag → CheeseEdWest
9 days ago edited
Is the Public Still FDA's #1 Client? Almost Half of Agency Funding Derives from Industry
https://trialsitenews.com/i...

FDA Willfully Blind on the Safety of COVID-19 Vaccination
https://www.bmj.com/content...
https://www.globalresearch....
1 0 • Reply • Share ›

Cat's Meow
10 days ago
Any physician who still believes these "vaccines" are safe and effective has a rock for a head.
14 0 • Reply • Share ›

GarySummers → Cat's Meow
10 days ago
Ones owned by Big Pharma!
2 0 • Reply • Share ›

Guest → Cat's Meow
8 days ago
They are no longer physicians in the usual meaning. They exist to do Pharma's bidding or they will not have jobs. Just like Germany in WW2. Tough choice to train to be a doctor that long just to have an evil master tell you to harm others or you will starve.
0 0 • Reply • Share ›

Erin O'Brien
10 days ago
Oh for goodness sakes. It's not the elderly. It's not men under forty. It's not children. it's not pregnant women. It's EVERYONE. ANYONE who takes this damn bio-weapon is at risk of getting blood clots. Can we please just call it for what it is? When the hell are we getting our apology? When are they going to make repairs to the public? The unemployed? I'm sick of this! I don't care what the 'studies' say. It's time for accountability. period.
12 0 • Reply • Share ›

tag → Erin O'Brien
10 days ago
I agree. Enough of the charts and graphs. these bio weapon jabs are killing people. WTF is so hard for the wooden head government to see?
3 0 • Reply • Share ›

farmerflag → tag
9 days ago
2 0 • Reply • Share ›

tag → farmerflag
9 days ago
He's one busy snake isn't he. Lucifer must be so proud of his son.
0 0 • Reply • Share ›

SHENZI → tag
9 days ago edited
You're expecting the government to "SEE" the evil that the government has created?!

Although in the 60s I developed a healthy mistrust of government: That hasn't changed; in fact, it has grown exponentiallyalong with corruption.

The fact is, your government doesn't care about you, and doesn't want you well! They want you fat, sick poor and nearly dead or dead.

It's up to us. WE THE PEOPLE. As John Lennon said, the people hold all the power.
POWER TO THE PEOPLE!! ✊🏾✌️💪
1 0 • Reply • Share ›

Guest → Erin O'Brien
8 days ago
What is happening is the weirdest, scariest thing I've experienced in my lifetime. I have had an aversion to vaccines my entire life. So have my parents. Therefore I was highly suspicious from the outset about why an experimental shot would be pounded so heavily in the mainstream media. The ads for the flu are bad enough. I find it unreal that with all the alternate sites out there that those 'intelligent people' who had a choice, refused to do the research necessary to find out what horrid, severe consequences awaited them if they chose to turn a blind eye. And then have the nerve to ridicule those who didn't join the 'flock'. Madness.
2 0 • Reply • Share ›

Jen
10 days ago
It's not just blood clotting problems in the elderly, it's blood clotting problems in many who took that jab.
9 0 • Reply • Share ›

kaoshispano → Jen
9 days ago
It must be a combination of MIOCARDITIS and clotting in arteries... so, a little big problema for shooted in EGO of the NWO.
1 0 • Reply • Share ›

farmerflag → kaoshispano
9 days ago edited
Dr. Peter McCullough a top cardiologist, said the heart injury due to the vaccine is around 10-100 times higher than the troponin seen in natural infection. Worsening matters, the doctor states that when kids develop myocarditis after the vaccine, 90% require immediate hospitalization to prevent heart failure

Dr. Charles Hoffe has been practicing medicine for 28 years in a small, rural town in British Columbia.
The problem he has seen are microscopic clots in his patients' tiniest capillaries.
This is an absolutely new phenomenon."
These micro-clots are too small to show up on CT scans, MRI, and other conventional tests,
such as angiograms, and can only be detected using the D-dimer blood test,
a standard test that indicates whether blood clots are being actively formed
somewhere within a person's vascular system.
see more
2 0 • Reply • Share ›

SHENZI → farmerflag
9 days ago
SCARY and EVIL
1 0 • Reply • Share ›

Chase Sheridan
10 days ago
A lot of older folks "died suddenly" from clotting illnesses as well as others that are experiencing actual blood clots and surviving that are NOT included in this research because their doctors refuse to suggest it's even a possibility. Mother, died 4/3/21 from heart attack 21 days from 2nd jab, Mother-in-Law died 4/9/21 from a massive stroke 17 days from 2nd jab (both women survived a bout with Covid prior to taking the jabs) Husband's sister's Brother in law died of a heart attack after getting the first two jabs, I don't have the dates for him. My Brother took initial series of jabs, then got very sick with Covid, then took two boosters and had to have emergency surgery in both legs for large clots preventing him from walking.
My brother is an intelligent very accomplished 60 year old adult, yet even with all this evidence staring him in the face and clotting his legs, he stubbornly refuses to even consider the jab might be involved.
8 0 • Reply • Share ›

SHENZI → Chase Sheridan
9 days ago edited
It's so shocking to me how blind people have chosen to be around this! The truth was clear as day to me from the very beginning when my gut screamed "NOOOOOOOOO!!!"

My gut has never lied to me; not once.
The same cannot be said about our government and BIG PHARMA and BIG HARM.

TRUST YOUR GUT!!

" Ye shall know the Truth, and the Truth shall set you Free.."

✨ JESUS
3 0 • Reply • Share ›

tag → Chase Sheridan
9 days ago
I am so sorry for you. I think most of us have known someone who either died or was injured by these safe and effective bio weapons but you have had a LOT to deal with. Stay strong in your knowledge.
2 0 • Reply • Share ›

Guest → Chase Sheridan
8 days ago
In the land of the blind, the one-eyed man is king. You have my sympathies on the loss of so many family members. You have my respect for knowing how to do research and not be duped into behaving like a clueless sheep. Be well, STAY well and enjoy life while we all can.
1 0 • Reply • Share ›

zark
10 days ago edited
This was analyzing data on elderly only.
This applies to the population 24 to 64 also in a big way. See Died Suddenly.
8 0 • Reply • Share ›

SHENZI → zark
9 days ago
Yeah, " Died suddenly"

UH-HUH.
0 0 • Reply • Share ›

gemma
10 days ago
I'm wondering how many people are or were aware that they're participating in a large ongoing experiment.
7 0 • Reply • Share ›

tag
10 days ago
I'm considered elderly I guess. Not vaxxed with the bio weapon but does being shed on by others put me at the same risk? I've had "something" 3 times since Dec 2020. is this assault on our health ever going to end? I seldom go anywhere and do nothing socially. Just tired of these bouts with flu/cold like symptoms and trying to breathe. .Trusting the medical "protocols" is something that just isn't going to happen for me. I guess like many of us, we are on our own.
6 0 • Reply • Share ›

Ruth Butros → tag
9 days ago
Have you tried high dose liposomal C? Having a hard time shaking a cough/low fever for six weeks, but this seems to be helping. Praying for your healing.
4 0 • Reply • Share ›

tag → Ruth Butros
9 days ago
Yes, I take that . I'm taking 3000 units but thinking about upping it to 5000. What dose do you take?
0 0 • Reply • Share ›

SHENZI → tag
9 days ago edited
Hi Tag!
When you say "trying to breathe", what do you mean exactly?
I'm just wondering about your symptoms if you wouldn't mind sharing because I didn't get the bio weapon jab either & the last few years my breathing capacity has diminished considerably which is very difficult for me because I am a singer and Ive always had the lungs of Pavarotti. Now I have no power I have no wind beneath my wings and it has derailed my whole singing career not to mention what this chronic exhaustion has done to my life in general.
I spend most days in bed. and if I have to go out I need a forklift powered by sheer force of will.
Thank you for your share. I wish for recovery of your health. I wish that for us all.
1 0 • Reply • Share ›

tag → SHENZI
9 days ago
Hi Shenzi For me the breathing was more like asthma which I have never had before. Occasionally it would go into wheezing and It is better than it was but I still get short of breath with any exertion. The coughing was exhausting! I have used several homeopathic remedies that have helped during an attack, automodium tartaricum will give me almost instant relief. After 3 weeks of this current bout, which was more like the flu I think, I started Ivermectin and I am finally feeling pretty good. I too was suffering from fatigue to the point I would sleep as much as 15 hrs a day and still need a short afternoon nap many days. I also do many vitamin supplements and FORCE myself to eat. My golden years are tarnished!
1 0 • Reply • Share ›

Voyt Regnal
10 days ago
Jessica Rose explains these 'clots' as essentially not clots, but rather PLAQUES of proteins !
Here is her interview with the Rebel News reporter. It is just her hypothesis, but very intriguing and gruesome :

These structures themselves, Rose says that "they definitely appear to be proteins. They definitely don't belong there. They're definitely not blood clots. What I'm wondering is if they're not an overproduction of a component of the clotting mechanism. It still remains a mystery."

https://www.rebelnews.com/p...
6 0 • Reply • Share ›

Nod → Voyt Regnal
9 days ago
It is not a mystery at all. It is graphene oxide. And that is the reasons of the research project called the covid 19 pandemic.

Graphene Oxide is the favoured substance for the injectable transmitters that will be the control method for future generations.

"Understanding the effect of nanomaterials on protein functional and biophysical properties is of fundamental importance in the area of bio-nanotechnology. "
https://jnanobiotechnology....

While they cannot seem to make it work the way they want, I guess they needed more test subjects, and now they have billions of test subjects.

==

"Graphene oxide is the hot topic in biomedical and pharmaceutical research of the current decade. However, its complex interactions with human blood components complicate the transition from the promising in vitro results to clinical settings. Even though graphene oxide is made with the same atoms as our organs, tissues and cells, its bi-dimensional nature causes unique interactions with blood proteins and biological membranes and can lead to severe effects like thrombogenicity and immune cell activation. "

https://pubs.rsc.org/en/con...
4 0 • Reply • Share ›

GrouchyMathGrad
10 days ago
I checked my calendar, but it's not April Fool's day. FDA researchers are finding problems with the COVID "vaccine"? What gives?
6 0 • Reply • Share ›

Joe Poisson
10 days ago
It is sad, have you checked you Bluetooth? There are branded people everywhere, the jab gave them a mac address. Imagine the mayhem that's going to come out of this, FDA is likely in on it, and it begins to explain why people dropping dead are seeing something horrible before they just drop. It is getting far more nasty out here, even the fresh graves emit a mac address.
5 0 • Reply • Share ›

tag → Joe Poisson
10 days ago
Since the beginning of the lock down when the 5-G towers were going up everywhere under disguise it was clear to any with some common sense this technocracy had something to do with this. Ask the sheep to give up their phones? No, they would rather give up their freedoms and their lives for twitter, fakebook and google. Poor souls.
2 0 • Reply • Share ›

SHENZI → tag
9 days ago
I would like to have the courage to give that all up and go back to landline!!
1 0 • Reply • Share ›

tag → SHENZI
9 days ago
I'm seriously considering it!
0 0 • Reply • Share ›

SHENZI → Joe Poisson
9 days ago edited
And how about untainted blood banks should you need a transfusion? What kind of blood are you going to get and do unvaccinated blood banks exist in this country? That is a whole other concern.
1 0 • Reply • Share ›

GarySummers
10 days ago edited
Wife almost Died Twice from Blood clots in the Lungs!

They Suppressed Ivermectin, Hydroxy, Etc, so they could have EUA for the Jabs and make Billions$ Evil!
Plus #200 Members of Congress took Ivermectin, and Congress Exempted themselves from the Jabs Mandates!

'BOMBSHELL: 'Veritas Documents Reveal DC Bureaucrats Had Evidence "Ivermectin and Hydroxychloroquine" Were Effective in Treating COVID" — BUT HID THIS FROM PUBLIC"
https://www.thegatewaypundi...

* "Documents stored on a "TOP SECRET" folder on the computers of the Defense Advanced Research Project Agency (DARPA) prove that the medicines "Ivermectin, Hydroxychloroquine and Interferon were PROVEN "Curative" of COVID-19 in April, 2020" – 'the cures were buried' as "Top Secret."
and concluded:
*"The revelation of these documents, sneakily stored in a TOP SECRET folder on government computers prove that the federal government of the United States KNEW in April, 2020, the entire "COVID-19 Pandemic" was completely curable through the use of these common medications..."
The proof is in provided in the January 10, 2022, Project Veritas video at

https://www.projectveritas....

*"Ivermectin (identified as curative in April 2020) works throughout all phases of illness because it both inhibits viral replication and modulates the immune response. Of note, chloroquine phosphate (Hydroxychloriquine, identified April 2020 as curative) is identified in the proposal as a SARSr-CoV inhibitor, as is interferon (identified May 2020 as curative)."

4 0 • Reply • Share ›

farmerflag ↪ GarySummers

9 days ago edited

Fauci Approved Chloroquine, Hydroxychloroquine 15 Years Ago to Cure Coronaviruses;

https://www.globalresearch....

2 0 • Reply • Share ›

Gary Brown

9 days ago

Population control and thinning the herd so to speak? You betcha!

Nov 16, 2022 Leading British Cardiologist, Dr. Aseem Malhotra, and Dr. Peter McCullough Independently Come to Same Conclusion

"The Covid mRNA vaccine has likely played a significant role or been a primary cause of unexpected cardiac arrests, heart attacks, strokes, cardiac arrhythmias, and heart failure since 2021..."

https://petermcculloughmd.s...

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